Docket No.: S63.2N-14369-US03

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Scott Smith

**Application No.:** 10/630562

Filed: July 30, 2003

For: Helically Formed Stent/Graft Assembly

**Examiner** Suba Ganesan

Group Art Unit: 3774

Mail Stop <u>Appeal Brief-Patents</u> Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## REPLY BRIEF

This is a Reply Brief for the above-identified application in response to the Examiner's Answer of January 22, 2009.

A Notice of Appeal was filed in this case on October 8, 2008. Subsequently, an Appeal Brief was filed on January 9, 2009. The fees required under §1.17(b) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

## Argument

At pages 3-4 of the Examiner's Answer, the Examiner asserts that the motivation to combine U.S. Patent No. 6,352,561 to Leopold et al. (hereinafter "Leopold") and U.S. Patent No. 6,165,210 to Lau et al. (hereinafter "Lau") "being: providing a stent with greater surface area to promote attachment to the helically wound graft material." Examiner's Answer dated February 18, 2009, page 3, paragraph 3, lines 5-7. The Examiner, however, fails to explain how a planar stent could somehow have greater surface area than a similarly constructed, but non-planar, stent.

Neither Leopold nor Lau disclose, teach or suggest that a planar stent will have greater surface area than a corresponding helically wound stent. Moreover, the Examiner fails to explain how such a modification of a stent from a planar orientation to a helical orientation or vice versa will so modify the surface area of the stent. Thus, the Examiner has failed to establish a *prima facie* case of obviousness pursuant to MPEP § 2142, which states, "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness."

Furthermore, MPEP § 2142 discusses how a proper obviousness determination is to be made:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

The Examiner is clearly using impermissible hindsight reconstruction in an attempt to arrive at the present invention. Accordingly, the Examiner's hindsight reconstruction is in violation of MPEP § 2142 and KSR International Co. v. Teleflex Inc., which states, "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." 82 USPQ2d 1385, 1379 (U.S. 2007) (citing Graham v.

John Deere, 383 U.S. 1, 36 (1966) (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight")). As there is no indication from the prior art that the alleged planar stent of Lau has greater surface area, the Examiner's alleged motivation to combine is erroneous. Thus, the rejected claims are non-obvious over the prior art.

Moreover, Leopold teaches away from the Examiner's asserted motivation to combine references. A "reference teaches away if it leaves the impression that the product would not have the property sought by the applicant." 31 USPQ2d at 1132, citing with approval *In re Caldwell*, 138 USPQ 243, 245 (CCPA 1963).

Leopold teaches that it is undesirable to maximize helical graft coverage of its underlying stent. Leopold, column 9 lines 25-35. Leopold further teaches that maximizing graft coverage of its underlying stent will result in tearing of the graft material and/or delamination of the stent and graft material. Leopold, column 9, lines 33-37. Thus, Leopold teaches away from the Examiner's asserted motivation to combine references, i.e., greater surface area for promotion of attachment. The Examiner clearly fails to explain how one of ordinary skill in the art would combine the references with such teachings being directly divergent to the motivation offered by the Examiner's Answer.

Furthermore, the proposed motivation to combine would render the prior art unsatisfactory for its intended purpose. Specifically, by increasing the surface area of the stent to promote attachment to the helically wound graft material, as suggested by the Examiner, the device of Leopold would be more likely to delaminate. As stated in MPEP § 2143.01, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).)

Thus, a person having ordinary skill in the art would not be motivated to combine Lau and Leopold as the Examiner suggests, and the claims of the immediate application are patentable over the cited art.

In essence, the Examiner has improperly combined the references in an attempt to arrive at the present invention. Clearly, the only motivation to combine and modify the

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references is hindsight reconstruction using the Appellant's application as a roadmap. As such an attempt is impermissible, Appellant respectfully requests allowance.

## Conclusion

For at least the reasons discussed above, claims 1, 3, 6-8, 12, and 13 are patently distinct over the cited art. Consequently, reversal of the rejection is respectfully requested.

Respectfully submitted,

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